

Access to Transplantation

Task 1: Assess current policies and the potential impact of the Final Rule on access to transplantation services for low-income populations and racial and ethnic minority groups, including the impact of state policies (under Title XIX of the Social Security Act) regarding payment for services for patients outside of the state in which the patients reside.

Abstract. There is very little research describing or explaining differences in access to liver transplantation services across racial, ethnic, and income groups. Therefore, the committee's findings are based on a small number of studies, most pertaining to kidney transplants, that report differences between white and African American populations or income classes and on the committee's own analysis of patient waiting times on liver transplantation lists. The published evidence reveals that African American and low-income kidney patients of all racial and ethnic groups are slower to be placed on waiting lists and, once on a waiting list, African Americans do not receive kidney transplants as quickly as whites. Well-known biological and socioeconomic factors, and lack of access to health care in general, undoubtedly play large parts in this disparity. African Americans may also be referred for liver transplants more slowly than whites, but once patients are referred, there appears to be little or no racial disparity in transplantation. The committee found no unequivocal evidence one way or the other on whether broader organ sharing would result in either closure of small transplant centers or, in the event of some such closures, a reduction in minority access. The most important predictors of equity in access to transplant services lie outside the transplantation system in access to health insurance and high-quality health services.

The committee was charged with determining what, if any, impact the Final Rule would have on access to transplantation services by low-income and minority populations. Although African Americans represent about 12 percent of the U.S. population, they comprise 27 percent of the patients diagnosed with end-stage renal disease. This is due to a variety of factors, including a higher incidence among them of hypertension and diabetes, but it underlines the need for analyzing all the possible effects of the Final Rule. Conducting this analysis required the committee to examine the determinants of access and how current policies affect access in order to draw conclusions about the potential impact of the changes proposed in the Final Rule. The very limited number of studies ad-

addressing these issues made this a challenging assignment, and the committee cautions that its findings must be considered provisional rather than conclusive.

The committee reviewed several articles that examine whether minorities have equal access to transplantation. Although almost all of these articles deal with kidney transplantation, the committee believes that some of the factors that bear on curtailed minority access to kidney transplants are also likely to bear on access to other solid organ transplants, although data on these issues are limited.

Lower access by African Americans to kidney transplantation is well documented (Alexander and Sehgal, 1998; Eggers, 1995). Much of the disparity appears to be due to the fact that African Americans are not placed on waiting lists as quickly, or in the same proportion, as their white counterparts. Moreover, once they are placed on a waiting list, African Americans do not receive kidney transplants as quickly as whites (Alexander and Sehgal, 1998; Eggers, 1995; DHHS, 1998c; Kasiske et al., 1991).

African Americans appear to fare somewhat better with respect to liver transplants than is the case with kidneys. Eckhoff and colleagues (1998) reviewed liver transplantation performed at the Alabama Organ Center and concluded that African Americans may experience a delay in referral to the center for evaluation or may not be referred at all, compared to the white population. However, they also concluded that once patients were referred, there were no racial disparities in being accepted onto the waiting list or in receiving a transplant. They suggested that access to health care, distrust of the medical community, lower socioeconomic status, and a lack of understanding about liver transplantation on the parts of both physicians and patients could be factors that influence the disparities in patient referrals. The DHHS Inspector General also found that the waiting times of African Americans for livers was quite similar to those of whites (DHHS, 1998c).

The committee's own analysis of waiting list data for 1995-1999 showed that for livers, African Americans comprised 8 percent of the list and received 9 percent of the transplants. These results indicate that the racial disparity in transplantation observed among patients on waiting lists for kidneys is not observed among patients waiting for livers. It does appear, however, that African Americans enter the list and receive liver transplants when they are sicker, relative to other racial groups. A greater percentage of African Americans are both listed and transplanted in status 1 (12 percent listed and 14 percent transplanted) relative to status 2 (10 percent listed and 8 percent transplanted) or status 3 (7 percent listed and 7 percent transplanted). The fact that African Americans are listed in disproportionately high numbers in status 1 reinforces the suggestion that initial access to health care and to referrals for transplant evaluation is an important impediment for African Americans with liver disease.

FACTORS AFFECTING ACCESS

Factors that might influence waiting list entry and account for differences in transplantation rates can be characterized broadly as: (1) socioeconomic factors; (2) severity of illness, general health status, and biological and medical suitability for transplantation; (3) characteristics of the transplant centers; and (4) in the case of kidney transplantation, patients' attitudes about dialysis versus transplantation.

Socioeconomic Factors

Ozminkowski and colleagues (1997), among others, have identified socioeconomic status as a major factor in determining whether kidney patients are able to get on a waiting list, accounting for one-third of the disparity between African Americans and whites. Patients with annual incomes greater than \$40,000 were twice as likely to be added to a waiting list within 2 years of their first end-stage renal disease service as those with incomes less than \$10,000 per year, and African Americans were disproportionately represented in the latter group. However, once a patient was placed on a waiting list, socioeconomic status seemed to have had little influence on whether the patient receives a transplant. A similar analysis by Alexander and Sehgal (1998) found black-white differences in transplantation even after controlling for income, but also found that the primary barrier for poor people as a group was gaining access to the waiting list.

The committee heard allegations that low-income patients were sometimes considered unsuitable candidates for kidney transplantation because of concerns about their ability to pay for immunosuppressive drugs. The committee could find only limited evidence to support this claim. For example, a telephone survey of four of the five renal transplant centers in Virginia found that 2 percent of all transplants performed over a 6.5 year period were lost to noncompliance due to inaffordability (Holman, 1999). On the other hand:

1. Medicare pays for these drugs, for virtually all kidney transplant patients, for 3 years post transplant.
2. Dosages, and therefore cost, are significantly reduced after three years.
3. Medicaid has no time limit for drug coverage.
4. There are a variety of state programs and private organizations (e.g., the American Kidney Foundation) that assist transplant patients in obtaining these medications.

The committee concluded that, although some patients might need additional help in maintaining immunosuppressive medication, implementation of the Final Rule is not likely to add to those numbers.

Biological Factors

Biological differences among racial and ethnic groups appear to be a factor in explaining the differential rates of transplantation. This is more important for kidney transplantation, which uses histocompatibility testing in matching organs and recipients, than it is for other solid organs, which rely on matching by blood type.

Histocompatibility testing works to the disadvantage of African Americans in two ways. First, the serological reagents currently used for such testing were developed primarily in whites and are not as reliable when used for African Americans. This problem may be alleviated in the future, however, by recent technological advances using molecular characterization of the genetic loci that give rise to histocompatibility antigens. Second, African Americans exhibit much greater heterogeneity in their histocompatibility antigens than whites, which makes it much more difficult to locate a fully matched organ in the pool of available donors. This problem could be alleviated to some degree by increasing organ donation among African Americans, although the high degree of heterogeneity within the African American populace means that successful matches will not necessarily increase in proportion to increased donation. De-emphasizing HLA matching would also result in more African Americans getting kidneys, though at the cost of a decrease in graft and host survival.

Another possible reason for the longer wait times for African American kidney patients is that nonwhite patients tend to survive longer on dialysis than do whites (Held et al., 1987). The reason for this is unknown, but adjustment for case mix, transplantation rates, withdrawal from dialysis rates, and initial treatment modality, although reducing the white-nonwhite disparity, did not eliminate the survival advantage for nonwhite dialysis patients (Mesler et al., 1999).

Other Factors

Ozminkowski et al. (1997) examined the influence of severity of renal disease, type of dialysis, contraindications for transplantation, and self-reported health and functional status, but found that none of these factors had a significant effect on racial disparities in terms of either access to a waiting list or receiving a kidney transplant. They did find that patient attitudes toward transplantation constituted a major factor in the racial disparities in both placement on a waiting list and receipt of a transplant. African Americans were less positive about the medical and health outcomes of kidney transplantation than whites and much more likely to express religious objections to transplantation, as well as uneasiness about having a dead person's organ in one's own body. However, a recent report by Ayanian and colleagues (1999) found black and white patients equally likely to report that they wanted a transplant, and similar in their expectations that transplantation would improve their quality of life.

POTENTIAL CLOSURE OF SMALL TRANSPLANT CENTERS

One of the arguments against the Final Rule is that it will cause some of the smaller liver transplant centers to close, forcing some patients to travel greater distances to be placed on a waiting list and receive a transplant. Some argue that this would be an insurmountable obstacle for poor patients and minorities.

The view that low-volume liver transplant centers would be forced to close if the Final Rule were implemented is apparently grounded on the assumption that since such centers currently have fewer status 1 or status 2A patients on their waiting lists, or have patients with shorter accumulated waiting times, a broader sharing arrangement that gave priority to status 1 and status 2A patients, and also took waiting time into account, would result in smaller centers' receiving fewer donated organs, with a corresponding decrease in the economic viability of these centers.

The committee was not persuaded by this argument. Even if the premise is a reasonably accurate characterization of the current situation for some of the low-volume transplant centers, the committee was not willing to assume it would remain unchanged after implementation of the Final Rule. The transplantation arena is dynamic and evolving. As policies and practices change, transplant centers and transplant patients will respond and adapt. Broader organ sharing may well increase the prospects that a patient listed at a low-volume transplant center will obtain a suitable matching organ. Thus, low-volume transplant centers may begin to increase the number of status 1 and status 2 patients on their waiting lists. In addition, the committee, later in this report (see Chapter 5), recommends that waiting times be discontinued as a factor in allocating organs among status 3 patients. These and other possible changes in the current allocation policies might dramatically alter the status quo. Moreover, the committee anticipates that the Department and the OPTN would fashion a transition process that would address these concerns. Given the paucity of evidence on this issue, this phase-in period should include close attention to impact on both access of minority and low-income populations, and the viability of small centers.

There is some preliminary information that counters the argument that broader sharing under the Final Rule would adversely affect small transplant centers. Beginning in January 1998, New York State began sharing donated livers statewide for patients of all statuses. This arrangement encompasses four OPOs, six liver transplant centers, a population of 18 million, and more than 300 liver transplants per year. Contrary to the argument put forward by opponents of the Final Rule, during the first year of statewide sharing the smallest transplant centers in New York State experienced an increase in organs allocated to them, and the largest center experienced a small decrease (Charles Miller, Recanati/Miller Transplantation Institute, The Mount Sinai Hospital, personal communication, April 23, 1999). Preliminary evidence for 1999 indicates that this trend is continuing. Although the committee does not consider this proof that the same will occur in other parts of the country under broader organ shar-

ing, it does believe, in the absence of evidence to the contrary, that it is a plausible outcome.

The committee examined the proposition that access to transplantation on the part of minorities would be adversely affected if low-volume centers were to close. It did so by analyzing 1998 data supplied by UNOS (Mary Ellison, UNOS, personal communication, May 3, 1999) on the number of African Americans and the number of Hispanics who received transplants at each center, as well as the number in each group who were on the waiting list of each transplant center that year. Three separate analyses were conducted, using different criteria to identify transplant centers relevant to the argument.

First, the committee identified 12 transplant centers that did 25 or fewer liver transplants in 1998 and were the only transplant centers in their communities. Of the total of 181 transplants done by these 12 centers, 3 of the liver recipients were African Americans and 23 were Hispanics (which were predominantly performed in two centers).

In the second analysis, the committee identified 27 transplant centers that did 15 or fewer transplants in 1998 and were located in communities with at least two transplant centers. These 27 centers did a total of 193 liver transplants, of which 26 were African American and 38 were Hispanic.

Finally, the committee looked at the waiting lists at the seven smallest transplant centers, each of which was the only center in its community. A total of 239 patients were on the waiting lists of these seven centers in 1998. Of these, 15 were African Americans (all at one center) and 18 were Hispanics.

Although the committee was unwilling to draw definitive conclusions from this brief analysis, these figures do seem to suggest that small transplant centers do not differentially serve minorities' access to liver transplantation at this time. The committee had sought to do a similar analysis for low-income patients, but it was not able to obtain any data on the socioeconomic status of patients transplanted or on waiting lists.

The committee also approached this issue by looking for evidence that an increase in the distance from a transplant patient's home to the transplant center (which would result from the closure of a small transplant center closer to home) would be an impediment to access. No direct examination of this factor was found, but Ozminkowski and colleagues (1997) reported that neither the distance from the patient's home to the nearest kidney transplant center (more than 50 miles versus less than 50 miles) nor the volume of transplants done by the nearest center was associated with differences in access to either a waiting list or a transplant. To the contrary, they suggested that the consolidation of current waiting lists into larger regional lists might help reduce disparities in access by giving waiting list patients access to a wider range of donor organs.

Ozminkowski's conclusion that distance from the patient's residence to the transplant center did not affect access would appear to be contradicted by Tuttle-Newhall and colleagues (1997), who studied patients admitted to a North Carolina hospital with a diagnosis of liver disease. They found that the likelihood of such patients' receiving a liver transplant at one of the two transplant centers in

North Carolina was greater for those living closer to the centers. They also found that access was influenced by a variety of other factors, including age, gender, type of disease, and payer status. However, the committee notes an important limitation of this study, which would suggest caution in interpreting its results. The study included only patients who received their transplants at one of the two transplant centers in North Carolina; the researchers noted that more than half (136 of 261) of the North Carolina residents receiving liver transplants during the study period received their transplants at centers in other states. Moreover, the analysis included all patients admitted to a hospital with liver disease, rather than being limited to those whose condition indicated that a liver transplant was appropriate. The study did not report whether an analysis was done for the effects of race or socioeconomic status.

POTENTIAL IMPLICATIONS OF MEDICAID PAYMENT POLICIES

All third party payers have rules about when and where covered patients may get a transplant, including state Medicaid programs, which cover low-income patients. The committee reviewed current state Medicaid policies regarding payments for transplantation to determine whether potential transplant recipients who are eligible for Medicaid might be adversely affected by changes in the current transplantation system proposed under the Final Rule. Again, the major concern expressed by opponents of the Final Rule is that it would result in the closure of smaller transplant centers and would decrease access on the part of those who depend on Medicaid to pay for transplants.

Based on the information available to the committee, it appears that the most established solid organ transplants—kidney, heart, and liver—are a covered service in nearly any state (see paragraph 15, pages 501ff of the CCH Medicare and Medicaid Guide, ND). Coverage for pancreas and lung transplants is less consistent across states. Several states limit coverage of transplants to patients who are categorically eligible for Medicaid, but most include coverage for both categorically and medically needy eligible individuals.* Some states have set restrictions on the medical conditions for which transplants will be funded, and many require prior approval from the state Medicaid agency for some or all transplants. Some states do not specifically address organ transplants in their plan, presumably treating them as one of many unspecified, mandatory, inpatient hospital services, subject to the test of “medical necessity.” There were no data available to the committee to assess the effectiveness of these policies in securing access to transplantation for those eligible for Medicaid.

Of interest to the committee is whether states will pay for transportation costs when a patient must travel from his or her residence to a distant transplant

*The reader is referred to Section 1902(a)(10) of the Social Security Act (42 USC 1396a(a)(10) for explanation of the varying types of Medicaid eligibility.

center. Under the federal regulations governing Medicaid, states must “ensure necessary transportation for [patients] to and from” the provider of care (42 CFR 431.53). “Transportation” is further defined to include related travel expenses, such as meals and lodging en route to and from medical care and while receiving care, both for the patient and, if necessary, for an attendant (42 CFR 440.170(a)). Payments for food and lodging are often marginal, however, and many states may restrict payment for transportation to the amount needed to reach the nearest available provider. Thus, if there is a transplant center located in a state, the state Medicaid plan may limit payments to transportation to this center. However, if there is no center in the state, payment will be made for transportation to and treatment in the nearest available transplant center. Thus, it appears that broader organ sharing resulting from implementation of the Final Rule is not likely to have a significant adverse effect on those who are dependent on Medicaid for their health care.

CONCLUSIONS

The committee did not find credible evidence that broader sharing or the Final Rule would result in the closure of smaller transplant centers. Moreover, even if smaller centers were to close, the committee was unable to conclude that it would have a significant adverse impact on access to organ transplantation on the part of minority and low-income patients. This does not mean, however, that the committee failed to recognize that there are serious concerns about equitable access that must be addressed. It only means that the committee believes that these problems will not be exacerbated if broader sharing is given a reasonable implementation. Broader sharing may even serve to alleviate some of these problems.

The committee notes that the Final Rule places responsibility on the Organ Procurement and Transplantation Network Board of Directors to develop:

Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:

- (i) Ensuring that patients in need of a transplant are listed without regard to ability to pay or source of payment;
- (ii) Procedures for transplant hospitals to make reasonable efforts to make available from their own resources, or obtain from other sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;
- (iii) Recommendations to private and public payers and service providers on ways to improve coverage of organ transplantation and necessary follow-up care; and
- (iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities. (DHHS, 1998b, p.16334)

The larger problems of equitable access to transplantation occur prior to a patient being put on a waiting list for a transplant; they take the form of inadequate health insurance coverage and inadequate access to primary care, proper diagnosis and treatment, and referral for transplant evaluation.